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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/611,835	07/07/2000	Brent R. Stockwell	50164/002002	6924
21559	7590	09/23/2004	<div>EXAMINER</div> <div>TRAN, MY CHAU T</div>	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			<div>ART UNIT</div> <div>PAPER NUMBER</div> <div>1639</div>	
DATE MAILED: 09/23/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/611,835	STOCKWELL ET AL.	
	Examiner	Art Unit	
	MY-CHAU T TRAN	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 89-156 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 89-156 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>7/12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 6/29/2004 is acknowledged and entered.
2. Claims 89, 114, 135, and 149 were amended by the amendment filed on 12/15/2003.
3. Claims 1-88 have been canceled by the amendment filed on 11/8/02.
4. Claims 89-156 are pending.
5. Claims 89-156 are treated on the merit in this Office Action.

Maintained Rejections

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
7. Claims 89-156 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stylli et al. (US Patent 5,985,214).

Stylli et al. teaches an automated method and system for identifying chemicals having useful activity such as biological activities of chemicals and collecting informations resulting from such a process (col. 6, lines 1-24). The method comprise of testing a therapeutic chemical for modulating activity of a target such as cell surface proteins in a cell based assay (col. 38,

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lines 46-67; col. 39, lines 1-9; col. 43, lines 6-9). The method comprises dispensing the reagents (compounds) into the addressable sample wells, which contains a predetermined volume of the sample (test cells) (col. 6, lines 25-40; col. 8, lines 14-18). The method can individually screen at least 25,000 selected and discrete chemicals or chemical libraries wherein the chemicals are structurally related base on activity relationships (i.e. a combination of compounds) (col. 37, lines 44-51). Various method of detection of the compound interaction with the target includes fluorescent measurement such as FRET (fluorescence resonance energy transfer) (col. 27, lines 29-35; col. 28, lines 15-17; col. 39, lines 1-67 thru col. 42, lines 1-23).

The method of Stylli et al. does not expressly disclose that the chemical compounds tested are forty-nine unique combinations of seven different compounds.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include testing of forty-nine unique combinations of seven different compounds in the method of Stylli et al. One of ordinary skill in the art would have been motivated to include testing of forty-nine unique combinations of seven different compounds in the method of Stylli et al. because the number of combinations of compounds to be tested for the affect of biological property would be a choice of experimental design and is considered within the purview of the cited prior art. Additionally, it has been held that “[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA1955). Furthermore, one of ordinary skill in the art would have had a reasonable expectation of success in testing of forty-nine unique combinations of seven different compounds

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in the method of Stylli et al. since the taught method would need no modification other than increasing the amount of compound combinations that do not materially affect the method steps.

Response to Arguments

8. Applicant has enquired for clarification if claims 149-153 are allowable. It is noted that claims 149-156 were inadvertently omitted in the rejection under 35 USC 103(a) and claims 149-156 are not allowed.

9. Applicant's arguments directed to the rejection under 35 USC 103(a) as being unpatentable over Stylli et al. (US Patent 5,985,214) for claims 89-156 were considered but they are not persuasive for the following reasons.

Applicant alleges that the method of Stylli et al. is not obvious over the presently claimed method because 1) Stylli et al. do not hint at the claimed inventive concept of multi-compound screening, i.e. screening a desired two or higher order combination of compounds; 2) the fact pattern of *In re Aller* is not applicable to the Stylli reference and the presently claimed method.

Applicant's arguments are not convincing since the method of Stylli et al. is obvious over the presently claimed method.

1) Stylli et al. do hint at the claimed inventive concept of multi-compound screening, i.e. screening a desired two or higher order combination of compounds. Stylli et al. discloses "*in practicing the methods of the invention, the products or compositions can be used alone or in combination with one another, or in combination with other therapeutic or diagnostic agents,*" i.e. screening a combination of compounds (see e.g. col. 44, lines 20-23). Thus the degree of

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combination of compounds, i.e. a desired two or higher order, would be a choice of experimental design or optimum or workable range. Furthermore, the examiner agree with the applicant that the method of Stylli et al. individually screen at least 25,000 selected and discrete chemicals or chemical libraries. However, the chemicals being screen in the method of Stylli et al. are structurally related base on activity relationships, and thus does not exclude that the chemical can be derive from "combination of compounds.

2) The fact pattern of *In re Aller* is applicable to the Stylli reference and the presently claimed method. The fact pattern of *In re Aller* is whether the changes such as temperature and concentration may impart patentability to a process if the particular ranges claimed produce a new and unexpected result, which is different in kind and not merely in degree from the result of the prior art. This is applicable to the Stylli reference and the presently claimed method in that the claimed number of combination of compounds, i.e. a desired two or higher order, of the claimed process is merely different in degree and not in kind from the number of combination of compounds of the Stylli reference process, i.e. the number of combination of compounds used in the claimed process would not produce a new and unexpected result. Additionally, applicant has not shown any criticality of the claimed number (range) of combination of compounds, i.e. a desired two or higher order, to the presently claimed method. Thus the fact pattern of *In re Aller* is applicable to the Stylli reference and the presently claimed method.

Therefore, the method of Stylli et al. is obvious over the presently claimed method, and the rejection is maintained.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MY-CHAU T TRAN whose telephone number is 571-272-0810. The examiner can normally be reached on Mon.: 8:00-2:30; Tues.-Thurs.: 7:30-5:00; Fri.: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANDREW WANG can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
September 17, 2004


ANDREW WANG
SUPERVISORY PATENT EXAMINER
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